Medical devices regulations and the Medical Devices Agency

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The Medical Devices Agency (MDA) was established in September 1994 as an executive arm of the Department of Health to promote the safe and effective use of devices. In particular its role is to ensure that whenever a medical device is used, it is:

- Suitable for its intended purpose
- Properly understood by the professional user
- Maintained in a safe and reliable condition.

Its primary responsibility is to ensure that medical devices achieve the potential to help healthcare professionals give patients and other users the standard of care they have a right to expect. In order to fulfil this role it has six main functions: investigating adverse incidents; providing advice and guidance; negotiating European directives and implementing and enforcing regulations on medical devices; contributing to standard setting on medical devices; evaluating medical devices and providing consultancy advice to users and purchasers; and providing support services for these activities. Its website enables access to all its publications and notices (www.medical-devices.gov.uk).

Case Scenario

Pansy suffered from a chronic lung condition which required frequent courses of antibiotics. As her veins were poor and cannulation was difficult, a passport was inserted into a vein in her arm in which antibiotics and other solutions were administered. After three courses of antibiotics over the course of several weeks, the nurses had difficulty in administering the medication through the passport but finally succeeded. Subsequently, during a routine X-ray of her lungs, it was discovered that the tube connected with the reservoir had become disconnected and had moved down the vein towards the heart.

WHAT IS A MEDICAL DEVICE?

The definition of a medical device used by the MDA is based upon the European Directive definition (European Union Directive 93/42/EEC) (*Figure 1*).

Annex B to Safety Notice 9801 from the MDA (1998a) gives examples of medical devices. See also the website (www.medical-devices.gov.uk). It covers the following:

- Equipment used in the diagnosis or treatment of disease, monitoring of patients, e.g. syringes and needles, dressings, catheters, beds, mattresses and covers, and other equipment
- Equipment used in life support, e.g. ventilators, defribillators
- Equipment used in the care of disabled people, e.g. orthotic and prosthetic appliances, wheelchairs and special support seating, patient hoists, walking aids, pressure care prevention equipment
- Aids to daily living, e.g. commodes, hearing aids, urine drainage systems, domiciliary oxygen therapy systems, incontinence pads, prescribable footwear
- Equipment used by ambulance services (but not the vehicles themselves), e.g. stretchers and trolleys, resuscitators
- Other examples of medical devices include condoms, contact lenses and care products, intrauterine devices.

Medical devices regulations require that as from 14 June 1998 all medical devices placed on the market (made available for use or distribution even if no charge is

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Any instrument, apparatus, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of contraception

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

Figure 1. Definition of a medical device. From: European Union Directive 93/42/EEC.

made) must conform to 'the essential requirements' including safety required by law, and bear a CE marking as a sign of that conformity (SI 1994/3017, Directive 93/42/EEC).

Although most of the obligations contained in the regulations fall on manufacturers, purchasers who are positioned further down the supply chain may also be liable, e.g. for supplying equipment which does not bear a CE marking or which carries a marking liable to mislead people (MDA, 1998b). This is the requirement of the EC Directive on medical devices (Directive 93/42/EEC). The manufacturer who can demonstrate conformity with the regulations is entitled to apply the CE marking to a medical device. The essential requirements include the general principle that:

> **'A device must not harm patients or users, and any risks must be outweighed by benefits'**
> (***Directive 93/42/EEC***).

Design and construction must be inherently safe, and if there are residual risks, users must be informed about them. Devices must perform as claimed, and not fail as a result of the stresses of normal use. Transport and storage must not have adverse effects. Essential requirements also include prerequisites in relation to the design and construction, infection and microbial contamination, mechanical construction, measuring devices, exposure to radiation, built-in computer systems, electrical and electronic design, mechanical design, devices which deliver fluids to a patient, and function of controls and indicators. Exceptions to these regulations include the following:

- Invitro diagnostic devices (these are covered by separate regulations which came into force in 2000)
- Active implants (covered by the Active Implantable Medical Devices Regulations, Directive 90/385/EEC)
- Devices made specially for the individual patient ('custom made')
- Devices undergoing clinical investigation
- Devices made by the organization ('legal entity') using them.

In January 1998, the MDA issued a device bulletin (MDA, 1998b) giving guidance to organizations on implementing the regulations. The MDA has powers under the Consumer Protection Act 1987 to issue warnings or remove devices from the market (see next article in this series for the Consumer Protection Act 1987).

Table 1. Checklist for health professionals

Do I know how to handle the medical devices in my unit?
What preparation have I been given in how to use a medical device and was the preparation formalized and recorded or ad hoc?
How was my competency to use this equipment safely assessed?
Am I familiar with the instructions on how to use this piece of equipment and any warning labels?
When was this equipment last serviced?
Do my junior staff colleagues know how to use equipment?
What is the cleaning and/or decontamination procedure and my responsibilities?
Do I know who is responsible for risk management in my organization?
Do I know how to report an adverse incident?
Do I know who my Medical Devices Agency liaison officer is?

Source: MDA (2001)

CLASSIFICATION OF DEVICES

Devices are divided into three classes according to possible hazards, class 2 being further subdivided:

- Class 1 with a low risk, e.g. a bandage
- Class 2a medium risk, e.g. a simple breast pump
- Class 2b medium risk, e.g. a ventilator
- Class 3 high risk, e.g. an intra-aortic balloon.

Any warning about equipment issued by the MDA should be acted upon immediately. Failure to ensure that these notices are obtained and acted upon could be used as evidence of failure to provide a reasonable standard of care.

ADVERSE INCIDENT REPORTING PROCEDURES

In 1998, the MDA issued a safety notice requiring healthcare managers, healthcare and social care professionals and other users of medical devices to establish a system to encourage the prompt reporting of adverse incidents relating to medical devices

to the MDA (MDA, 1998a). The procedures should be reviewed regularly, updated as necessary, and should ensure that adverse incident reports are submitted to the MDA in accordance with the notice.

WHAT IS AN ADVERSE INCIDENT?

The Safety Notice defines an adverse incident as 'an event which gives rise to, or has the potential to produce, unexpected or unwanted effects involving the safety of patients, users or other persons' (MDA, 1998a). An adverse incident may be caused by shortcomings in:

> **'...the device itself, instructions for use, servicing and maintenance, locally initiated modifications or adjustments, user practices including training, management procedures, the environment in which it is used or stored or incorrect prescription'** ***(MDA, 1998a).***

Where the incident has led to or could have led to the following:

> **'Death; life-threatening illness or injury; deterioration in health; temporary or permanent impairment of a body function or damage to a body structure; the necessity for medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure; unreliable test results leading to inappropriate diagnosis or therapy'** ***(MDA, 1998a).***

Minor faults or discrepancies should also be reported to the MDA.

LIAISON OFFICER

The Safety Notice suggests that organizations should appoint a liaison officer who would have the necessary authority to:

- Ensure that procedures are in place for the reporting of adverse incidents involving medical devices to the MDA
- Act as the point of receipt for MDA publications
- Ensure dissemination within their own organization of MDA publications
- Act as the contact point between MDA and his/her organization.

GUIDANCE FROM THE MDA

The MDA has published guidance on the responsibilities of individuals and organizations (www.medical-devices.gov.uk). It has also published a checklist for health professionals (*Table 1*) to ask themselves before they use medical devices (MDA, 2001).

APPLICATION OF LAW TO THE SITUATION IN THE CASE SCENARIO

In relation to the 'Case scenario' it is essential that as soon as it is found that the possibility of such a separation between the tubing and the reservoir could take place, a report must be sent to the MDA.

It should be clear within the NHS trust who has the responsibility of informing the liaison officer of the defect, so that the MDA can warn the manufacturers and all users of this particular equipment of the danger.

On the facts it does not appear that Pansy has suffered any direct harm, although there may have been increased discomfort during the administration of medicines. Fortunately, the defect was discovered before serious harm occurred. If Pansy had died as a result of the defect, her relatives may have had a claim under the consumer protection legislation, which will be considered in the next article.

CONCLUSION

The checklist provided by the MDA is a useful starting point for any nurse not familiar with the medical devices regulations. Assistance can be obtained within an NHS or primary care trust by contacting the MDA liaison officer. At the very least, practitioners should ensure that they are on the circulation list for any relevant warnings from the MDA and that they in turn know how to make known to the appropriate person an adverse incident should it arise. Personal access to the MDA website would also ensure that practitioners keep up to date. BJN

MDA (1998a) *SN 9801: Reporting Adverse Incidents Relating to Medical Devices.* January 1998. MDA, London

MDA (1998b) *Medical Device and Equipment Management for Hospital and Community-based Organizations.* MDA DB 9801 January 1998. MDA, London

MDA (2001) *One Liners February 2001 (Issue 11).* MDA, London

KEY POINTS

- The Medical Devices Agency (MDA) was established in September 1994 as an executive arm of the Department of Health to promote the safe and effective use of devices.
- The checklist provided by the MDA is a useful starting point for any nurse not familiar with medical devices regulations.
- Practitioners should ensure that they are on the circulation list for any relevant warnings from the MDA and that they in turn know how to make known to the appropriate person an adverse incident should it arise.